REMARKS

Claims 1 through 6, 8 through 18, and 21 through 25 are in the application and are presented for consideration. By this amendment, Applicant has made minor changes two claims 3 and 12 to address formal issues. No new issues have been presented.

Claim 3 has been rejected under 35 U.S.C. 112, second paragraph, as being indefinite. Applicant has now made changes to claim 3 to address the issues which have been raised. It is Applicant's position that the claim as presented is clear, definite and in full conformance with the requirements of the statute.

Claim 12 has been rejected under 35 U.S.C. 112, second paragraph, as being indefinite. Applicant has now made changes to claim 12 to address the issues which have been raised. It is Applicant's position that the claim as presented is clear, definite and in full conformance with the requirements of the statute.

Claims 1-6, 12, 14, 15, 18 and 21-24 have been rejected under 35 U.S.C. 102(b) as being anticipated by WIPO Publication 01/72352 to Medvedev.

Applicants respectfully traverses the rejection as it is Applicant's position that Medvedev fails to teach and fails to suggest each of the features as specified by the rejected claims. It is requested that the rejection be removed and that the claims be allowed as presented.

It is Applicant's position that Medvedev does not disclose a method of determining pump faults. Instead, Medvedev discloses a control system for a rotary blood pump. A further aspect of the control system of Medvedev is that the control depends on the pump operating in a known and dependable manner. Medvedev is not concerned with detecting problems with the pump and instead assumes there will be reliable and predictable pump function.

The Medvedev system senses a current waveform, voltage waveform and rotational frequency waveform. Based on the sensed information, the operation of the blood pump is altered to control blood flow to a patient requiring blood flow support to satisfy the physiologic needs of the patient. Only electrical aspects relating to current, voltage and frequency are used for blood flow control. Medvedev presents the specific teaching that it is advantageous that the system is sensorless as no sensors for blood flow and no pressure sensor are provided. There is no detection of any fluid characteristics. Instead, fluid characteristics are inferred. A fair reading of Medvedev must consider that values of fluid characteristics are not actually known. The information obtained is based on the predicted result of operation and the correlation of such with the detected current waveform, voltage waveform and rotational frequency waveform. This is an indication of the likely hydraulic value, but it is not a detection of the actual hydraulic value.

The fundamental teachings of Medvedev are silent with regard to the need for determining faults during operation of a pump unit. The Medvedev reference is silent as to the desirability of such fault determination. Medvedev also teaches directly away from a sensing of hydraulic variables, namely there is no teaching of any determination of actual prevailing flow or fluid pressure.

In general Medvedev is concerned with the control of a blood pump. This includes controlling operation of the pump to control the overall system with regards to the physiologic conditions of the patient. The Medvedev reference does not consider malfunctions or consider faults in the pump unit itself.

The claimed invention considers detection of faults and isolation of the fault contributing factors in the pump unit. The invention is not concerned with the behavior of a patient as in

Medvedev. The nature of determining pump faults and the nature of sensorless monitoring of a the behavior of a patient in a blood pump system present a huge difference between Medvedev and the claimed invention. Fluid systems do have some aspects in common and the Medvedev reference discloses a fluid system with a conrolled pump. Some of the equations in Medvedev and in the present application are the same, but these describe standard relations that are known from basic physics. These equations are used for very different purposes in Medvedev as compared to the claimed invention. It is not possible to deduce the results described in the present application from the results of Medvedev.

Referring to claim 1:

Medvedev fails to teach and fails to suggest a method of determining pump faults.

Claim 1 requires both "providing an electrical detection means for detecting the electrical variables of the motor" and also "providing a hydraulic detection means for detecting the changing hydraulic variable of the pump." An important aspect of the invention is that this is two different sources of information. This considers issues of pump faults from both the motor side as well as the pump output side. Medvedev teaches what is referred to as a sensorless approach where no flow or pressure sensors are used. A current sensor 20, a voltage sensor 22 and a frequency sensor 24 are provided to provide current voltage and frequency signals. These relate to the operation state of the motor. A fair reading of Medvedev leads to the conclusion that Medvedev teachers providing an electrical detection means for detecting the electrical variables of the motor but does not teach providing a hydraulic detection means for detecting the changing hydraulic variable of the pump. This distinction alone renders the rejection untenable. However, various other aspects of the claimed combination are also neither taught nor suggested by Medvedev. Further, a discussion is

presented below regarding Medvedev teaching away from the present invention such that the invention as claimed is nonobvious in view of Medvedev.

Medvedev fails to teach the step of "detecting the hydraulic variable of the pump with the hydraulic detection means." Medvedev teaches that there is no detection of hydraulic variables such as flow and fluid pressure.

It appears that the rejection considers the use of an observed relationship between motor power and pump flow rate. The rejection appears to consider that a measurement of motor power and the use of the observed relationship between motor power and pump flow rate is a detection of a hydraulic variable. This is believed to be an unfair reading of the teachings of Medvedev. A relationship of pump function and blood flow based on motor input power only provides an indication of likely blood flow. Such use of a relationship or approximation of blood flow is not a detection of blood flow. Of course as to the present invention, the use of current and voltage (power) and also an indication of a hydraulic value based on the same current and voltage information is not at all the same as using two distinct and different sources of information. Medvedev does not teach detecting blood flow and actually teaches away from detecting any hydraulic characteristic. Instead, Medvedev teaches the well-known concept that a properly operating pump can deliver a volume rate of flow based on steady-state power – flow characteristics.

The rejection relies on the discussion in Medvedev relating to electrical power consumed by a motor being equal to the voltage times the current to meet the claimed limitation "providing a mathematical electrical motor model for generating a motor value from a mathematical linking of the detected electrical variables of the motor." However, with regard to the limitation relating to "providing a mathematical mechanical-hydraulic pump model for generating a pump comparison

value" the rejection only makes reference to the exclusively electrical signal based equations (4 and 5). There is no reference to any teaching of linking of the motor value (the output of the electrical-based models) and the detected hydraulic variable of the pump. No hydraulic variable is detected, no mathematical mechanical – hydraulic pump model is provided and no hydraulic variable is linked with the motor value (the output of the electrical-based models) in a mathematical mechanical – hydraulic pump model.

The failure of Medvedev reference to teach each feature as specified in the claims is quite significant. Claim 1 is a method to determine faults in a pump assembly. The parts of Medvedev that describe faults/events detection is concerned with physiological phenomena in the human body. The focus is on the heart rate and flow pulses (the patient's pulse). Claim 1 of the present application involves a system where two electrical variables and at least one hydraulic variable are measured. In Medvedev all is done in a "sensorless" manner, which in the Medvedev context means that only electrical variables are used and no hydraulic variables are measured. This means that it is impossible to do the fault detection and isolation proposed according to the present invention with the setup taught by Medvedev.

Medvedevalso fails to teach and fails to suggest generating the pump comparison value as claimed. Medvedev does not teach an input of the motor value and the detected hydraulic variable of the pump into the mathematical mechanical-hydraulic pump model as there is no detected hydraulic variable. There is also no predefined pump value and no comparing of the pump comparison value with the predefined pump value.

Referring to claim 2:

Equation 5 of Medvedev is used for calculating the power of the motor. The power of the motor then gives an indication (based on past calibration and observation) of the flow of the pump. In the context of claim 2 of the present application the power (current and voltage information) is used for detecting faults in the pump system and not for flow estimation. In fact flow estimation based on a power measurement is well known and has been used in Grundfos pumps for decades.

Referring to claim 3:

The discussion of Medvedev after Page 7, line 35 is concerned with faults/issues with the heart rate and physiologic conditions of a human patient and not of the pump. The discussion starting at page 9, line 25 of Medvedev is concerned with detection of the arterial pressure, which again is a physiologic condition. The claims of the present application are concerned with faults in the pump and not the system surrounding the pump. Only faults in the surrounding system (the physiologic aspects of the human patient) are handled in Medvedev, whereas pump fault are not handled at all according to the teaching of Medvedev. Claim 3 requires a determination of which type of fault has affected the pump. This is neither taught nor suggested by Medvedev. Claim 3 patentably defines over Medvedev.

Referring to claim 4:

Equation (3) in Medvedev is used for providing an indication of blood pressure. This pressure is then used for detection of physiologic phenomena. A curve is obtained from test data obtained in a previous bench pump. No fluid pressure is detected, but the detected motor information provides an indication of pressure. Claim 4 is addressed to measuring the pressure as

the hydraulic variable for the fault detection according to the present invention. This has no similarities with the calculation proposed by Medvedev. Claim 4 patentably defines over Medvedev.

Referring to claim 5:

Equation (4) in Medvedev is used for an indication of the likely hydraulic value. There is no teaching of any determination of an actual or prevailing flow or fluid pressure. Claim 5 is directed to measuring flow as the hydraulic variable of the claimed method of claim I. This has no similarities with the calculation proposed by Medvedev. Claim 5 patentably defines over Medvedev.

Referring to claim 6:

On Page 25 of Medvedev a standard method for flow estimation/indication (the likely hydraulic value) is presented. There is no teaching of any determination of an actual prevailing flow or fluid pressure. This method of flow estimation/indication has been used in Grundfos pump for two decades. Claim 6 involves measuring the difference pressure as the hydraulic variable of the method of claim 1. This has no similarities with the calculation proposed by Medvedev. Claim 6 patentably defines over Medvedev.

Referring to claim 12:

Medvedev is not concerned with detecting faults in the pump, but physiologic phenomena of the human patient. Claim 12 claims a method of detecting and isolating faults on the pump itself. Medvedev fails to teach or suggest the invention as claimed. Claim 12 patentably defines over Medvedev.

Referring to Claim 14:

Medvedev is concerned about the flow behavior of a human patient. Incorrect flow behavior, is not a feature of the pump. It is assumed the pump will operate as it did in the past. According to the system disclosed in the Medvedev reference, flow issues are caused by the behavior of the human patient. Claim 14 is concerned with faults in the pump, and not incorrect flow behavior. The invention does not characterize what an incorrect flow behavior is as the method does not involve knowledge of the normal behaviour of the system surrounding the pump. There is no fault detection or fault state that involves incorrect flow behaviour as this is not a fault in the pump.

Claim 14 relates to a method of changing the speed and thereby the operating point of the pump to better determine the cause of the fault with higher probability. In Medvedev the pump speed is controlled based on electrical signals and past correlation with flow for the given physiologic state of the human body. Medvedev fails to teach or suggest the invention as claimed in claim 14. Claim 14 patentably defines over Medvedev.

Referring to claim 15:

In Medvedev signal analysis of voltage, current and frequency are used to provide an indication of the likely behavior, which is used for indicating the condition of the patient. Medvedev teaches an analysis of the min and max values of the indication of the likely flow and the flow pulsation to indicate the likely condition of the patient.

The present invention uses a mathematical model approach for fault detection. This means

that the model describes the expected connections between signal values, and if these are not fulfilled it can be decided if a fault has occurred and the cause of this fault. This is very different form a signal analysis approach as used in Medvedev. Medvedev fails to teach or suggest the invention as claimed in claim 15. Claim 15 patentably defines over Medvedev.

Referring to claim 18:

It is correct that electrical measurements are used both in the syetem taught by Medvedev and in the method and device according to the invention. In Medvedev the electrical measurements are used via calculations to obtain estimates of the hydraulic variables. According to the claimed device at least one hydraulic variable is detected with a hydraulic detection means. This actual value (this measurement) is used together with the electrical measurement to detect malfunctions or faults in the pump unit it self. This is information from two distinct sources. According to Medvedev, faults in the pump unit are not considered, only indications of changes in the physiologic condition of the patient are of interest. The Medvedev system relies on the expected and proper function of the pump to provide indications of changes in the physiologic condition of the patient. Medvedev fails to teach or suggest the invention as claimed in claim 18. Claim 18 patentably defines over Medvedev.

Referring to claim 21:

The device according to the invention as claimed in claim 21 is an intelligent pump unit that contain an evaluation means with an intelligent fault handling algorithm. It is correct that Medvedev also includes an algorithm as part of the blood pump system. The algorithm taught by Medvedev

is a control algorithm that handles control in accordance with the patient needs. The algorithm of the evaluation means of the claimed device is a fault detection algorithm that detects faults in the pump. This is essentially different from a pump control system such as a feedback control. There exist other pump systems with associated control systems, such as the proportional control of Grundfos pumps. Teachings of control features do not suggest the evaluation means with an intelligent fault detection algorithm according to the invention. Medvedev fails to teach or suggest the invention as claimed in claim 21. Claim 21 patentably defines over Medvedev.

Referring to Claim 22:

What is described in Medvedev is a control circuit that measures an error between the wanted signal (the reference) and the real signal, and takes action to account for the difference (by changing the motor power). This is standard control theory – feedback control. According to the invention a device is provided to detect faults in the system in the form of wear and component breakdown. When this has happened a fault notification (warning) is transmitted to the users of the pump. Medvedev fails to teach and fails to suggest transmitting any signals to the user of the pump. Claim 22 patentably defines over Medvedev.

Referring to Claim 23:

Medvedev is interested in the condition of the patient. Aspects of the condition are considered based on only voltage, current and frequency sensors for the pump motor. This allows an estimation or determination of the likely behavior of the pump flow. Medvedev does not measure

or detect the pump flow and the actual flow is not ever known according to the system of Medvedev. The flow is estimated based on a calculation using current, voltage and frequency of the motor and based on past electrical and mechanical measurements. The device of the method of the invention uses at least

one actual detected hydraulic value, and uses a smart algorithm to decide if there is a malfunction or a fault in the pump. Medvedev fails to teach or suggest the invention as claimed in claim 23. Claim 23 patentably defines over Medvedev.

Referring to Claim 24:

Claim 24 is directed to two electrical signals (supply voltage and current) and one hydraulic signal (pump pressure) being is used, from the "detection means" of claim 1. This is used to detect faults in the pump. This is information from several sources including the electrical and hydraulic detection. Medvedev teaches a method for estimating pressure/flow or determining the likely pressure/flow from the electrical signals. The calculation of estimated or likely flow is then used for controlling the power to the pump. This is a feedback control and is very different from the claimed method. Medvedev fails to teach or suggest the invention as claimed in claim 24. Claim 24 patentably defines over Medvedev.

Each of the claims presents a combination of features which, as a whole, is neither taught nor suggested by the prior art. Medvedev fails to teach or suggest each feature as specified in the claims. Further, the invention provides a combination of features which presents a method and a device which is very different from the method and device taught by Medvedev. Medvedev fails

to teach or suggest a method and a device for determining faults upon operation of the pump assembly. The structural features taught by Medvedev cannot be used to practice the inventive method. Medvedev fails to teach or suggest important concepts which are critical to the inventive method and device. Accordingly, applicant respectfully request that the rejection be reconsidered.

Further and favorable action on the merits is respectfully requested.

Respectfully submitted
for Applicant,

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ATTACHMENTS:
SHOULD ANY OTHER FEE BE REQUIRED, THE PATENT AND TRADEMARK OFFICE IS HEREBY REQUESTED TO CHARGE SUCH FEE TO OUR DEPOSIT ACCOUNT 13-0410.

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